



UNITED STATES PATENT AND TRADEMARK OFFICE

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JUL 15, 2004

Thomas Hoxie  
Novartis Pharmaceuticals Corp.  
Patent and Trademark Dept.  
564 Morris Ave.  
Summit NJ 07901-1027

In Re: Patent Term Extension  
Application for  
U.S. Patent No. Re. 34,878

Dear Mr. Hoxie:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. Re. 34,878 for a period of 1,260 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the PSC Forms Download Website: <http://forms.psc.gov/forms/FDA/fda.html> (<http://forms.psc.gov/forms/FDA/Fda-3542.pdf>).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

Attention: Claudia Grillo

RE: STARLIX® (nateglinide)  
FDA Docket No.: 01E-0367

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## (12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : Re. 34,878  
(45) ISSUED : March 14, 1995  
(75) INVENTOR : Shigeshi Toyoshima, et al.  
(73) PATENT OWNER : Ajinomoto Co., Inc.  
(95) PRODUCT : STARLIX® (nateglinide)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. Re. 34,878 based upon the regulatory review of the product STARLIX® (nateglinide) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,260 days

from March 28, 2006, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 14th day of July 2004.

*Jon W. Dudas*

Jon W. Dudas  
Acting Under Secretary of Commerce for  
Intellectual Property and Acting Director of the  
United States Patent and Trademark Office